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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,562

05/12/2006

Emilio Enrique Bunel

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PATENT DIVISION

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EXAMINER

KLINKEL, KORTNEY L

ART UNIT

PAPER NUMBER

1611

NOTIFICATION DATE

DELIVERY MODE

01/30/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/579,562	<b>Applicant(s)</b> BUNEL ET AL.	
	<b>Examiner</b> Kortney L. Klinkel	<b>Art Unit</b> 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 9/18/2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-12,17-19 and 22 is/are pending in the application.
- 4a) Of the above claim(s) 17-19 and 22 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3-7 is/are allowed.
- 6) ☒ Claim(s) 1, and 8-12 is/are rejected.
- 7) ☒ Claim(s) 1,3,4 and 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :5/12/2006, 9/19/2006 and 7/10/2008.

## **DETAILED ACTION**

### ***Claims***

Receipt is acknowledged of the amendments and remarks filed 9/18/2008.

Claims 2, 13-16, 20-21 and 23-28 were canceled.

Claims 1, and 3-10 were amended.

Claims 1, 3-12, 17-19 and 22 are pending in the instant Office action.

### ***Election/Restriction***

Applicant's election with traverse of Group I, now claims 1, 3-11, in the reply filed on 9/18/2008 is acknowledged. The traversal is with respect to the restriction of Group II (pharmaceutical formulation containing compounds of claim 1) from Group I (compounds). Applicant argues that Group II includes all the limitations of claim 1, which is in Group I, and therefore restriction is improper. This argument is found persuasive, and accordingly Group II (now claim 12), has been rejoined to Group I. Restriction of Group III (claims 17-19 and 22), drawn to methods of treatment is still deemed appropriate.

The requirement is still deemed proper and is therefore made FINAL.

Claims 17-19 and 22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Election was made **with** traverse in the reply filed on 9/18/2008.

Acknowledgement is also made of Applicant's election of the compound of claim 8 in the response filed 9/18/2008. The Examiner's search of this compound was found

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free of the prior art, and accordingly the search was expanded to include the full scope of all compounds recited in the instant claims.

In summary, claims 1, and 3-12 are under consideration in full.

### ***Information Disclosure Statement***

Acknowledgement is made of applicant's submitting information disclosure statements on 5/12/2006, 9/19/2006 and 7/10/2008. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

### ***Specification***

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### ***Notes***

The Examiner would like to point out an observation, which currently poses no problems, but may raise issues in the event of potential future amendments. All of the compounds recited in the instant claims fall within the genus of claim 1 with the exception of compounds CC-11 to CC-17 and CC27 to CC-44 of independent claim 7. The definitions set forth in claim 1 for R<sub>BOH</sub> do not currently encompass the substitution

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present in compounds CC-11 to CC-17 and CC27 to CC-44. Because claim 7 is an independent claim, there currently is no problem.

### ***Claim Objections***

Claims 1, 3-4 and 10 are objected to because of the following informalities:

Claim 1 is missing a period at the end of the claim. The comma after the phrase "-5-tetrazolyl" should be a period.

Claim 10 currently recites "The prodrug derivative of the A compound..." This claim should recite "The prodrug derivative of a compound...", the second occurrence of the word "the" should be deleted and the letter "a" should be lower case.

Claims 3 and 4 currently recite improper Markush language. In claim 3, the word or following "1-hydroxycyclopentyl" under the definition for R<sub>BOH</sub> should be changed to and. Also, under the definitions for R<sub>C</sub>, the last two entries should read as follows:

-C(O)Nme-CH<sub>2</sub>-C(O)OH, and

-C(O)NMe-CH(Me)-C(O)OH.

Currently, the word or is incorrectly used and is placed after the wrong substituent listing. A period is also missing at the end of the claim.

In claim 4, the word or should be changed to and following the entry 3-ethyl-3-hydroxy-4-methylpentnyl, under the definitions for R<sub>BOH</sub>.

Appropriate correction is required.

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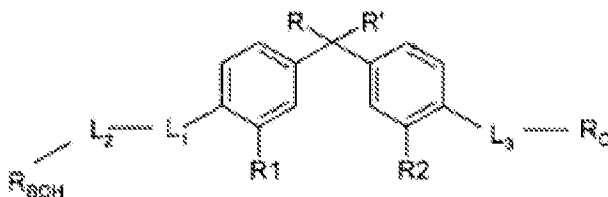
***Claim Rejections - 35 USC § 112 2<sup>nd</sup> Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 8-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the following compound:



However, claim 1 fails to recite a definition for L<sub>3</sub>. Based on compounds recited subsequent claims and the compounds recited in the specification examples, for the purposes of examination, the Examiner is interpreting L<sub>3</sub> to be a bond.

***Claim Rejections - 35 USC § 112 1<sup>st</sup> Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, and 8-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some compounds of claim 1 (those wherein R and R' are independently C<sub>1</sub> to C<sub>5</sub> alkyl), does not reasonably provide enablement for all compounds of claim 1, particularly those wherein R and R' together form a carbocyclig

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ring having from 3 to 8 atoms. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

All of the *Wands* factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The rejected invention is drawn to compounds of claim 1 in which all variables are indicated within the claim.

Relative skill of those in the art: The relative skill of those in the art is high.

Breadth of claims: The claims are extremely broad in that they encompass a large number of possible structural components for each variable of the compound.

State of the prior art/Predictability or unpredictability of the art: The skilled artisan would view that the synthesis of all possible variations of the compounds would require much experimentation.



Amount of guidance/Existence of working examples: More importantly, there are working examples present for only a subset of the possible variations of compounds recited in claim 1. In the instant case, the synthesis outlined in Scheme 1 for the genus of compounds encompassed in claim 1 provides adequate support for R and R' being C1-C5 alkyl. However, this synthesis, and the remainder of the specification as originally filed, fails to provide adequate written description for R and R' forming a carbocyclic ring having 3 to 8 carbon atoms. The synthesis as presented does not allow a carbocycle to form between R and R'. All working examples presented in the instant application have both R and R' as ethyl. Other than C1-C5 alkyl, Applicants describe no other R or R' that might be useful in the present invention.

Furthermore, applicant provides no working examples of a compound in which R<sub>C</sub> is -5-tetrazolyl.

Thus, Applicants have not described the genus of claim 1 in a manner that would allow one skilled in the art to immediately envisage, or make the compounds contemplated for use in the claimed compositions.

Lack of a working example is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.

Thus, the specification fails to provide clear and convincing evidence in sufficient support for making the claimed compounds as recited in the instant claims.

*Genetech*, 108 F.3d at 1366, states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “[p]atent

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protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable”.

Therefore, in view of the *Wands* factors as discussed above, e.g., the amount of guidance provided and the lack of working examples, to practice the claimed invention herein, a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

### ***Conclusion***

Claims 1, and 8-12 are rejected. Claims 3-7 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kortney Klinkel whose telephone number is (571)270-5239. The examiner can normally be reached on Monday-Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KLK

/Sharmila Gollamudi Landau/

Supervisory Patent Examiner, Art Unit 1611